

COF C

#23 PATENT  
M.T.D



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:

McCall, Catherine A.  
Tang, Liang

U.S. Patent No.: 6,703,360 B2

Issue Date: March 9, 2004

Atty. File No.: AL-7

For: "CANINE IL-13 RECEPTOR NUCLEIC  
ACID MOLECULES, PROTEINS,  
COMPOSITIONS THEREOF AND  
METHODS OF USE"

**REQUEST FOR CERTIFICATE OF  
CORRECTION OF PATENT  
FOR PTO MISTAKE**  
(37 C.F.R. 1.322(a))

<p align="center">CERTIFICATE OF MAILING</p> <p>I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE U.S. POSTAL SERVICE AS FIRST CLASS MAIL ADDRESSED TO COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VIRGINIA 22313-1450, THIS <u>27</u> DAY OF <u>April</u> 2004.</p> <p align="center">HESKA CORPORATION</p> <p>By: <u>Susan A. Gordon</u> Susan A. Gordon</p>	
---	--

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

**Certificate**  
**MAY 04 2004**  
**of Correction**

Dear Sir:

This is a request for a Certificate of Correction for a PTO mistake under 37 C.F.R. 1.322(a). Attached in duplicate is Form PTO-1050. The errors in this patent are obvious typographical or scanning errors. The correction in the title is supported by the Office Action dated October 23, 2002, wherein the Examiner requested a more descriptive title; Amendment and Response dated January 21, 2003, requesting entry of a new title; and Final Office Action, dated April 21, 2003, wherein Examiner acknowledges new title of invention. The correction to the claims can be found in the Amendment and Response After Final, filed August 12, 2003.

First page, title, please delete the title and replace with --CANINE IL-13 RECEPTOR NUCLEIC ACID MOLECULES, PROTEINS, COMPOSITIONS THEREOF AND METHODS OF USE--.

Column 219, line 21, please delete "region".

MAY 05 2004

Column 220, line 13, please delete "candid," and replace with --canid,--.

Column 222, line 8, please delete "NO:55, SEQ ID NO:55" and replace with --NO:55,  
SEQ ID NO:58--.

Respectfully submitted,

Dated: April 27, 2004

By: Richard J. Stepien

Richard J. Stepien, Ph.D.

Registration No. 50,668

Heska Corporation

1613 Prospect Parkway

Fort Collins, Colorado 80525

Telephone: (970) 493-7272

Facsimile: (970) 491-9976

UNITED STATES PATENT AND TRADEMARK OFFICE  
**CERTIFICATE OF CORRECTION**

PATENT NO. : 6,703,360 B2  
DATED : March 9, 2004  
INVENTOR(S) : Catherine A. McCall; Liang Tang

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

First page, Title, please delete the title and replace with --CANINE IL-13 RECEPTOR NUCLEIC ACID MOLECULES, PROTEINS, COMPOSITIONS THEREOF AND METHODS OF USE--.

Column 219, line 21, please delete "region".

Column 220, line 13, please delete "candid," and replace with --canid,--.

Column 222, line 8, please delete "NO:55, SEQ ID NO:55" and replace with --NO:55, SEQ ID NO:58--.

MAILING ADDRESS OF SENDER:

Heska Corporation  
Intellectual Property Dept.  
1613 Prospect Parkway  
Fort Collins, Colorado 80525

PATENT NO. 6,703,360 B2

MAY 05 2004

UNITED STATES PATENT AND TRADEMARK OFFICE  
**CERTIFICATE OF CORRECTION**

PATENT NO. : 6,703,360 B2  
DATED : March 9, 2004  
INVENTOR(S) : Catherine A. McCall; Liang Tang

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

First page, Title, please delete the title and replace with --CANINE IL-13 RECEPTOR NUCLEIC ACID MOLECULES, PROTEINS, COMPOSITIONS THEREOF AND METHODS OF USE--.

Column 219, line 21, please delete "region".

Column 220, line 13, please delete "candid," and replace with --canid,--.

Column 222, line 8, please delete "NO:55, SEQ ID NO:55" and replace with --NO:55, SEQ ID NO:58--.

MAILING ADDRESS OF SENDER:

Heska Corporation  
Intellectual Property Dept.  
1613 Prospect Parkway  
Fort Collins, Colorado 80525

PATENT NO. 6,703,360 B2

MAY 05 2004

UNITED STATES PATENT AND TRADEMARK OFFICE  
**CERTIFICATE OF CORRECTION**

PATENT NO. : 6,703,360 B2  
DATED : March 9, 2004  
INVENTOR(S) : Catherine A. McCall and Liang Tang

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title page.

Item [54], please delete the title and replace with -- **CANINE IL-13 RECEPTOR NUCLEIC ACID MOLECULES, PROTEINS, COMPOSITIONS THEREOF AND METHODS OF USE** --.

Column 219.

Line 21, please delete "region".

Column 220.

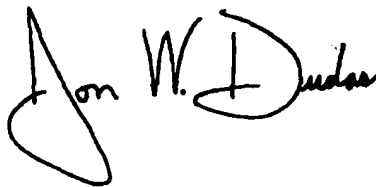
Line 13, please delete "candid," and replace with -- canid, --.

Column 222.

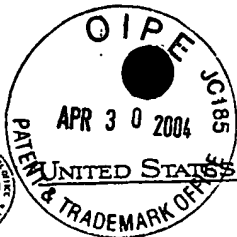
Line 8, please delete "NO:55, SEQ ID NO:55" and replace with -- NO:55, SEQ ID NO:58 --.

Signed and Sealed this

First Day of June, 2004

A handwritten signature in black ink, appearing to read "Jon W. Dudas". The signature is stylized with a large, looping initial "J" and a distinct "D".

JON W. DUDAS  
*Acting Director of the United States Patent and Trademark Office*



RJS/TAB/KTV

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,995	04/09/2001	Catherine A. McCall	AL-7	9579

26949 7590 10/23/2002

HESKA CORPORATION  
INTELLECTUAL PROPERTY DEPT.  
1613 PROSPECT PARKWAY  
FORT COLLINS, CO 80525

COPYCOPY

EXAMINER

SPECTOR, LORRAINE

ART UNIT PAPER NUMBER

1647

DATE MAILED: 10/23/2002

'02 OCT 28 RCV'D

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action

3 mo response due Jan 23, 2003  
w/ extensions to Apr. 23, 2003

DOCKETED

**Part III: Detailed Office Action**

**Notice:** Effective June 18, 2000, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1647.

**Restriction Requirement:**

Two restriction requirements were made in this application, see paper number 14.

In response to the first, Applicant's election of Invention I in Paper No. 15, filed 8/15/02, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

In response to the second, requiring applicants to elect among sequences, the Examiner spoke with applicant's attorney, Richard J. Stern, by telephone in August, 2002, requesting a clearer alignment of the various sequences. The attorney complied, supporting the arguments made in paper number 15 that examination of the claimed sequences would not present an undue burden. This argument is therefore, persuasive, and the second restriction requirement is **withdrawn**.

Claims 34 and 35 are rejoined with the elected group, as not presenting an undue search burden. Claims 53 and 54 are withdrawn from further consideration as being drawn to a non-elected invention. Claims 24, 25, 28-30, 34-40, 43-47 and 49-51 are under consideration.

**Formal Matters:**

The information disclosure statements submitted 8/23/01, 10/5/01 and 2/20/02. References by Kazuhiko et al. and Avery et al. have not been considered because they are merely sequences, the significance of which cannot be assessed in the absence of an alignment to the claimed sequences or alternatively a statement of relevance.

The title of the invention is not descriptive. A new title is required that is clearly indicative



ATTN. Non-Fee Amendment  
PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:

McCall, Catherine A.  
Tang, Liang

Group Art Unit: 1647

Examiner: Spector, Lorraine

AMENDMENT AND RESPONSE

Serial No.: 09/828,995

Filed: April 9, 2001

Atty. File No.: AL-7

For: "CANINE IL-13 RECEPTOR NUCLEIC  
ACID MOLECULES, PROTEINS,  
COMPOSITIONS THEREOF AND  
METHODS OF USE" (As Amended)

COPY  
COPY

<p align="center">CERTIFICATE OF MAILING</p> <p>I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, ADDRESSED TO BOX NON-FEE AMENDMENT, COMMISSIONER FOR PATENTS, WASHINGTON, DC 20231, THIS 21ST DAY OF JANUARY 2003.</p> <p align="center">HESKA CORPORATION</p> <p>By: <u>Susan A. Gordon</u> Susan A. Gordon</p>
--

Box Non-Fee Amendment  
Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

This response is directed to the Office Action with a mailing date of October 23, 2002.  
The Applicants would like to thank the Examiner for providing such a well-thought out and well-written review of the above-mentioned Application. Applicants found the guidance provided by the Examiner to be most helpful in their response. Prior to the Examiner's review of the Claims of the above-referenced Application, please enter the following amendments.

IN THE TITLE

Please delete the current title and enter the following new title:

"CANINE IL-13 RECEPTOR NUCLEIC ACID MOLECULES, PROTEINS,  
COMPOSITIONS THEREOF AND METHODS OF USE"

IN THE CLAIMS

Please cancel all claims without prejudice or disclaimer of the subject matter therein and enter the following new claims 60-80.

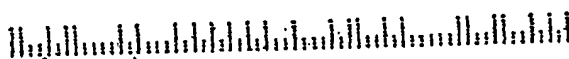




Heska Corporation  
Intellectual Property Dept.  
1613 Prospect Parkway  
Fort Collins, CO 80525

'03 FEB 3 RCVD

© 2003 USA 2¢

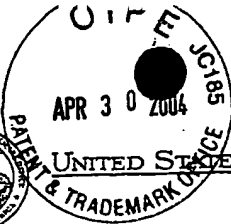


DOCKETED

DATE: January 21, 2003  
APPLICANT: Catherine A. McCall; Liang Tang  
SERIAL NO.: 09/828,995  
ATTY. FILE NO.: AL-7  
TITLE: CANINE IL-13 RECEPTOR NUCLEIC  
ACID MOLECULES, PROTEINS,  
COMPOSITIONS THEREOF AND  
METHODS OF USE" (As Amended)



RECEIPT IS HEREBY ACKNOWLEDGED OF:  
Amendment and Response; deposited with the  
U.S. Postal Service as First Class Mail this date.



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,995	04/09/2001	Catherine A. McCall	AL-7	9579

26949 7590 04/21/2003

HESKA CORPORATION  
INTELLECTUAL PROPERTY DEPT.  
1613 PROSPECT PARKWAY  
FORT COLLINS, CO 80525

COPY

DOCKETED

EXAMINER	
SPECTOR, LORRAINE	
ART UNIT	PAPER NUMBER

1647

DATE MAILED: 04/21/2003

18

'03 APR 24 RCV'D

Please find below and/or attached an Office communication concerning this application or proceeding.

Final OA  
2 mo response due 6/21/03  
3 " " 7/21/03  
w/ exts to 10/21/03

**Part III: Detailed Office Action**

Newly submitted claims 60-80 are pending.

**Formal Matters:**

5 The new title of the invention is acknowledged.

**Objections and Rejections under 35 U.S.C. §112:**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

10 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

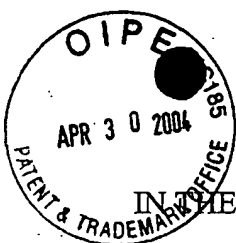
---

Claims 75-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15 Claim 75 is indefinite as it is not clear whether "a canine IL-13R $\alpha$ 2 protein domain" is intended to indicate that the entire IL-13R $\alpha$ 2 is a domain of the fusion protein, or alternatively that only one (of several) domains of IL-13R $\alpha$ 2 is present in the fusion protein. Claim 75 is also indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim says only that part (b) encodes a canine IL-13R $\alpha$ 2 protein domain, without any structural limitations. The specification as filed discloses two proteins,  
20 designated IL-13R $\alpha$ 1 and IL-13R $\alpha$ 2. Although the two presumably have different sequences and properties, the specification does not provide an adequate written description of the identifying features of the two, i.e. what would make a protein an IL-13R $\alpha$ 1 and not an IL-13R $\alpha$ 2, or vice versa, or even features that would distinguish either from other proteins. Thus, the metes and bounds of claim 75 cannot be determined, as the protein is referred to only by name, and as the specification  
25 fails to breath life and meaning into that name.

The remaining claims are rejected for depending from an indefinite claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:



ATTN: Mail Stop AF  
PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:

) Group Art Unit: 1647  
)

McCall, Catherine A.  
Tang, Liang

) Examiner: Spector, Lorraine  
)

Serial No.: 09/828,995

COPY

) AMENDMENT AND RESPONSE  
) AFTER FINAL  
)

Filed: April 9, 2001

Atty. File No.: AL-7

For: "CANINE IL-13 RECEPTOR NUCLEIC  
ACID MOLECULES, PROTEINS,  
COMPOSITIONS THEREOF AND  
METHODS OF USE"

CERTIFICATE OF FACSIMILE TRANSMISSION

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS  
BEING SENT BY FACSIMILE TRANSMISSION TO  
EXAMINER SPECTOR AT FAX NO. 703-308-0294,  
ADDRESSED TO MAIL STOP AF, COMMISSIONER FOR  
PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-  
1450, THIS 12TH DAY OF AUGUST 2003.

HESKA CORPORATION

By: \_\_\_\_\_

*Susan A. Gordon*

Susan A. Gordon

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

This Amendment and Response After Final is being sent in response to the Advisory Action mailed from the U.S. Patent and Trademark Office on August 6, 2003. In the event any fees are due with this response, please charge Deposit Account No. 081930. Prior to the Examiner's review of the Claims of the above-referenced Application, please enter the following amendments.

## AMENDMENTS TO THE CLAIMS

Please cancel Claims 62, 73, 74 and 77 and amend the remaining Claims as follows:

Claims 1-59 (Canceled)

60. (Currently amended) An isolated nucleic acid molecule selected from the group consisting of:

(a) an isolated nucleic acid molecule having an at least 50 contiguous nucleotide region identical in sequence to an at least 50 contiguous nucleotide region from SEQ ID NO:54, SEQ ID NO:56, SEQ ID NO:57, SEQ ID NO:59, SEQ ID NO:60, SEQ ID NO:62, SEQ ID NO:63, SEQ ID NO:64, SEQ ID NO:65, SEQ ID NO:67, SEQ ID NO:68 or SEQ ID NO:70;

(b) an isolated nucleic acid molecule comprising ~~an at least 60 nucleotide region that is a nucleic acid sequence~~ at least 95% identical ~~in to the sequence to an at least 60 contiguous nucleotide region from~~ of SEQ ID NO:54, ~~SEQ ID NO:56~~, SEQ ID NO:57, ~~SEQ ID NO:59~~, SEQ ID NO:60, ~~SEQ ID NO:62~~, SEQ ID NO:63, ~~SEQ ID NO:64~~, SEQ ID NO:65, ~~SEQ ID NO:67~~, or SEQ ID NO:68 or ~~SEQ ID NO:70~~, wherein said isolated nucleic acid molecule encodes a protein that binds a canine IL-13 protein; and

(c) an isolated nucleic acid molecule fully complementary to the isolated nucleic acid molecule of (a) or (b).

61. (Currently amended) The isolated nucleic acid molecule of claim 60, wherein said isolated nucleic acid molecule comprises a nucleic acid sequence ~~encoding an amino acid~~ sequence selected from ~~SEQ ID NO:55, SEQ ID NO:58, SEQ ID NO:61, SEQ ID NO:66 or SEQ ID NO:69~~ SEQ ID NO:54, SEQ ID NO:56, SEQ ID NO:57, SEQ ID NO:59, SEQ ID NO:60, SEQ ID NO:62, SEQ ID NO:63, SEQ ID NO:64, SEQ ID NO:65, SEQ ID NO:67, SEQ ID NO:68 or SEQ ID NO:70.

62. (Canceled)

63. (Reiterated) An isolated nucleic acid molecule selected from the group consisting of:

(a) an isolated nucleic acid molecule encoding a protein selected from the group consisting of:

(i) a protein comprising an amino acid sequence 95% identical to the sequence of SEQ ID NO:55, SEQ ID NO:58, SEQ ID NO:61, SEQ ID NO:66 or SEQ ID NO:69, wherein said protein binds a canine IL-13 protein; and

(ii) a protein comprising an at least 40 contiguous amino acid region identical in sequence to an at least 40 contiguous amino acid region from SEQ ID NO:55, SEQ ID NO:58, SEQ ID NO:61, SEQ ID NO:66 or SEQ ID NO:69; and

(b) an isolated nucleic acid molecule fully complementary to an isolated nucleic acid molecule of (a).

64. (Currently amended) An isolated protein selected from the group consisting of:

(a) a protein comprising an at least ~~50~~ 40 contiguous amino acid sequence identical to an at least ~~50~~ 40 contiguous amino acid sequence from SEQ ID NO:55, SEQ ID NO:58, SEQ ID NO:61, SEQ ID NO:66 or SEQ ID NO:69, ~~wherein said protein binds a canine IL-13 protein;~~ and

(b) a protein comprising an amino acid sequence ~~that is~~ at least 95% identical in sequence to SEQ ID NO:55, SEQ ID NO:58, SEQ ID NO:61, SEQ ID NO:66 or SEQ ID NO:69, wherein said protein binds a canine IL-13 protein.

65. (Reiterated) The isolated protein of claim 64, wherein said isolated protein comprises an amino acid sequence selected from SEQ ID NO:55, SEQ ID NO:58, SEQ ID NO:61, SEQ ID NO:66 or SEQ ID NO:69.

---

66. (Currently amended) An isolated chimeric nucleic acid molecule encoding a fusion protein, wherein said nucleic acid molecule comprises a first nucleic acid sequence encoding a carrier protein, and wherein said nucleic acid molecule further comprises a second nucleic acid sequence encoding ~~comprising a carrier protein domain and a canine IL-13R $\alpha$ 2 protein domain, wherein said canine IL-13R $\alpha$ 2 protein domain comprises an at least 40 contiguous amino acid region identical in sequence to an at least 40 contiguous amino acid region from SEQ ID NO:55,~~

SEQ ID NO:58, SEQ ID NO:61, SEQ ID NO:66 or SEQ ID NO:69, ~~and wherein said canine IL-13 $\alpha$ 2 protein domain binds a canine IL-13 protein.~~

67. (Reiterated) The chimeric nucleic acid molecule of claim 66, wherein said fusion protein comprises a linker sequence.

68. (Currently amended) The chimeric nucleic acid molecule of claim 66, wherein said carrier protein ~~domain~~ is an immunoglobulin Fc region.

69. (Currently amended) The chimeric nucleic acid molecule of claim 66, wherein said carrier protein ~~domain~~ is a canine immunoglobulin Fc region.

70. (Currently amended) The chimeric nucleic acid molecule of claim 66, wherein said carrier protein ~~domain~~ is a canine immunoglobulin gamma Fc region.

71. (Currently amended) The chimeric nucleic acid molecule of claim 66, wherein said ~~chimeric nucleic acid molecule comprises a~~ second nucleic acid sequence is at least 95% identical to a nucleic acid sequence selected from the group consisting ~~SEQ ID NO:71, SEQ ID NO:74, SEQ ID NO:77, SEQ ID NO:80 and SEQ ID NO:82~~ SEQ ID NO:54, SEQ ID NO:57, SEQ ID NO:60, SEQ ID NO:63, SEQ ID NO:65 and SEQ ID NO:68, and wherein said second nucleic acid sequence encodes a protein that binds a canine IL-13 protein.

72. (Currently amended) The chimeric nucleic acid molecule of claim 66, wherein said ~~IL-13 $\alpha$ 2 protein domain is encoded by~~ second nucleic acid sequence is selected from the group consisting of ~~SEQ ID NO:54, SEQ ID NO:57, SEQ ID NO:60, SEQ ID NO:63, SEQ ID NO:65 and SEQ ID NO:68~~ SEQ ID NO:71, SEQ ID NO:74, SEQ ID NO:77, SEQ ID NO:80 and SEQ ID NO:82.

73. (Canceled)

74. (Canceled)

75. (Currently amended) A fusion protein comprising a first ~~carrier protein~~ domain and a canine IL-13R $\alpha$ 2 protein second domain, wherein said first domain comprises the amino acid sequence of a carrier protein, and wherein the second domain comprises an at least 40 contiguous amino acid region identical in sequence to an at least 40 contiguous amino acid region from SEQ ID NO:55, SEQ ID NO:58, SEQ ID NO:61, SEQ ID NO:66 or SEQ ID NO:69.

76. (Currently amended) The fusion protein of claim 75, wherein said fusion protein comprises an amino acid sequence selected from the group consisting of SEQ ID NO:55, SEQ ID NO:58, SEQ ID NO:61, SEQ ID NO:66, SEQ ID NO:69, SEQ ID NO:72, SEQ ID NO:75, SEQ ID NO:78 and SEQ ID NO:81.

77. (Canceled)

78. (Currently amended) A therapeutic composition comprising ~~a nucleic acid molecule comprising a nucleic acid molecule encoding a protein selected from a canine IL-13R $\alpha$ 2 protein and the fusion protein of claim 75~~ the isolated protein of Claim 64.

79. (Reiterated) A method to regulate an immune response in a canid, said method comprising administering to said canid the therapeutic composition of claim 78.

80. (Currently amended) A method to produce a canine IL-13R $\alpha$ 2 protein, said method comprising:

(a) culturing a cell comprising a recombinant nucleic acid molecule selected from the group consisting of:

(i) an isolated nucleic acid molecule having an at least 50 contiguous nucleotide region identical in sequence to an at least 50 contiguous nucleotide region from SEQ ID NO:54, SEQ ID NO:56, SEQ ID NO:57, SEQ ID NO:59, SEQ ID NO:60, SEQ ID NO:62, SEQ ID NO:63, SEQ ID NO:64, SEQ ID NO:65, SEQ ID NO:67, SEQ ID NO:68 or SEQ ID NO:70;



(ii) an isolated nucleic acid molecule comprising ~~an at least 100 nucleotide region that is a nucleic acid sequence~~ at least 95% identical in sequence to an at least 100 contiguous nucleotide region from SEQ ID NO:54, ~~SEQ ID NO:56, SEQ ID NO:57, SEQ ID NO:59, SEQ ID NO:60, SEQ ID NO:62, SEQ ID NO:63, SEQ ID NO:64, SEQ ID NO:65, SEQ ID NO:67,~~ or SEQ ID NO:68 or ~~SEQ ID NO:70~~, wherein said isolated nucleic acid molecule encodes a protein that binds a canine IL-13 protein;

(iii) an isolated nucleic acid molecule encoding a protein comprising an amino acid sequence 95% identical to the SEQ of SEQ ID NO:55, SEQ ID NO:58, SEQ ID NO:61, SEQ ID NO:66 or SEQ ID NO:69, wherein said protein binds a canine IL-13 protein;  
and

(iv) an isolated nucleic acid molecule encoding a protein comprising an at least 40 contiguous amino acid region identical in sequence to an at least 40 contiguous amino acid region from SEQ of SEQ ID NO:55, SEQ ID NO:58, SEQ ID NO:61, SEQ ID NO:66 or SEQ ID NO:69, ~~wherein said protein binds a canine IL-13 protein; and~~

~~(v) an isolated nucleic acid molecule fully complementary to the isolated nucleic acid molecule of (i), (ii), (iii) or (v); and~~

(b) recovering said canine IL-13Ra2 protein.

## REMARKS

Claims 62, 73, 74 and 77 have been canceled.

Applicants have amended the remaining Claims so they now read in the style of allowed Claim 63. Specifically:

Claim 60 has been amended to remove reference to 60 contiguous nucleotide regions in part (b) so that the percent identity is now measured against the whole of the listed SEQ ID NO's.

Claim 61 has been amended to remove amino acid SEQ ID NO's and to specify specific nucleic acid SEQ ID NO's.

Claim 64 has been amended in part (a) to specify proteins have 40 (instead of 50) contiguous amino acids identical to the stated SEQ ID NO's. In addition, the language requiring the 40 amino acid region bind an IL-13 protein has been removed.

Claim 66 has been amended to clarify the different regions of the fusion protein. The term 'domains' has been removed and the chimeric nucleic acid molecule is now described as composed of two sequences whose characteristics are described in the claim.

Claims 68, 69 and 70 have been amended by the removal of the term 'domain'. Applicants believe the language of these claims, along with that of Claim 66 from which they depend, is now easier to read and understand.

Claim 71 has been amended to specify sequences within the chimeric nucleic acid molecule be 95% identical to stated SEQ ID NO's; in addition, a functional limitation has been added for the claimed nucleic acid molecules.

Claim 72 has been amended to specify particular sequences for the chimeric nucleic acid molecule.

Claim 75 has been amended to clarify the language. The claim now uses specific SEQ ID NO's instead of the term "IL-13R $\alpha$ 2 domain" when referring to portions of the fusion protein.

Claim 76 has been amended to included several more SEQ ID NO's already present in other Claims.

Claim 78 has been amended so the therapeutic composition now contains protein instead of nucleic acid molecules. This claim has also been made dependent from Claim 64.

Claim 80 has been amended in part (a)(ii) so that the percent identity is measured against the whole of the stated SEQ ID NO. Finally, a functional requirement for short amino acid sequences identical in sequence to regions from stated SEQ ID NO's has been removed.

Accordingly, Applicants submit no new matter has been entered into the Application.

## II. Rejections under 35 U.S.C. §112, second paragraph

The Examiner has rejected claims 75-79 as being indefinite for failing to point out and distinctly claim the subject matter which the Applicant regards as the invention. Specifically, the Examiner states the limitation 'canine IL-13R $\alpha$ 2 protein domain' is indefinite since the protein is referred to only by name and the claim lacks any associated structural limitation. Applicants note the term "IL-12R $\alpha$ 2 protein domain" has been removed and specific SEQ ID NO's have been added to the language of Claim 75 to provide a structural limitation.

## III. Rejections under 35 U.S.C. §112, first paragraph

The Examiner has rejected previous claims 60, 64, 66-70, 72-75 and 78-80 under 35 U.S.C. §112, first paragraph, stating that while the specification is enabling for "...nucleic acids disclosed as SEQ ID NO:54, 56, 57, 59, 60, 62-65, 67, 68 or 70 or fragments thereof (of specific lengths) or species which vary by codon degeneracy therefrom, as well as with proteins encoded thereby or fragments of said proteins that retain binding function...", it is not enabling for any nucleic acids only 95% identical to a 60 nucleotide fragment of any of said sequences nor nucleic acid molecules comprising as little as 40 nucleotides which encode proteins that bind canine IL-13. The Examiner further states the specification does not disclose which portion of the protein is required for binding activity and that undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope. Finally, the Examiner has stated the art of gene therapy, and in dogs in particular, is not considered to be routine or predictable in the art and in the absence of any specific guidance and working examples in the specification, claims to such therapy are not enabled.

Applicants note the claims have been amended to remove reference to short regions of a protein or nucleic acid molecule having some percentage identity with the given SEQ ID NO's. The claims have been drafted so that percent identities be compared to the whole of the given SEQ ID NO's. In addition, Applicants have removed any functional requirement from claims

referring to short regions of protein, or nucleic acid sequence, identical in sequence to regions of stated SEQ ID NO's.

With respect to claims referring to gene therapy, Applicants note such claims have been amended so that the therapeutic compositions now comprise protein instead of nucleic acid molecules.

#### Conclusion

Applicants have amended the Claims in view of the Final Office Action, mailed April 21, 2003, the Advisory Action, mailed August 6, 2003, and the telephone conversations with the Examiner on August 12, 2003. In view of the above amendments and remarks, Applicants believe the Claims are in condition for allowance and solicit such from the Examiner. Should any issues remain unresolved, or should the Examiner have any questions regarding this Application, the Examiner is invited to contact the undersigned.

Respectfully submitted,

Dated: August 12, 2003

By:



Richard J. Stern, Ph.D.  
Registration No. 50,668  
Heska Corporation  
1613 Prospect Parkway  
Fort Collins, Colorado 80525  
Telephone: (970) 493-7272  
Facsimile: (970) 491-9976

# Facsimile



## HESKA

*The Science of Caring  
for Companion Animals*

---

1613 Prospect Parkway  
Fort Collins, CO 80525  
970-493-7272 (t)  
970-491-9976 (f)

Date: August 12, 2003

PLEASE DELIVER THE FOLLOWING PAGE(S) TO:

Name: Examiner Lorraine Spector, Ph.D., Group Art Unit 1647

Facsimile Number: 703-308-0294

Telephone Number: 703-308-1793

Pages: 10 (including this cover page)

Subject: Attorney File No. AL-7

U.S. Patent Application Serial No: 09/828,995

From: Richard J. Stern, Ph.D. (970-493-7272 - Ext 4174)

---

CONFIDENTIALITY NOTICE

The documents accompanying this FACSIMILE transmission may contain confidential information which is legally privileged. The information is intended only for the use of the individual or entity named above. If you are not the intended recipient, or the person responsible for delivering it to the intended recipient, you are hereby notified that any disclosure, copying, distribution or use of any of the information contained in this transmission is strictly PROHIBITED. If you have received this transmission in error, please immediately notify us by telephone and mail the original transmission to us. Thank you.

```

*****
*                                     P.01
*                                     *
*          TRANSACTION REPORT          *
*                                     *
*                                     AUG-12-2003 TUE 02:40 PM
*                                     *
*   DATE  START  RECEIVER  TX TIME  PAGES TYPE  NOTE  M#  DP
*   -----
*   AUG-12 02:38 PM 17033080294  2' 45"   10  SEND   OK   204
*   -----
*                                     TOTAL :      2M 45S  PAGES:  10
*                                     *
*****

```

# Facsimile



## HESKA

*The Science of Caring  
for Companion Animals*

---

1613 Prospect Parkway  
Fort Collins, CO 80525  
970-493-7272 (t)  
970-491-9976 (f)

Date: August 12, 2003

PLEASE DELIVER THE FOLLOWING PAGE(S) TO:

Name: Examiner Lorraine Spector, Ph.D., Group Art Unit 1647

Facsimile Number: 703-308-0294

Telephone Number: 703-308-1793

Pages: 10 (including this cover page)

Subject: Attorney File No. AL-7